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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,375	06/06/2001	John G.K. Williams	20031000820	8990

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EXAMINER

STRZELECKA, TERESA E

ART UNIT PAPER NUMBER

1637

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/876,375

Applicant(s)

WILLIAMS ET AL.

Examiner

Teresa E Strzelecka

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 29-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II (claims 18-44) in Paper No. 10 is acknowledged. The traversal is on the ground(s) that claims from Groups I and II should be joined because these claims are drawn to an intact charge-switch NP probe, an enzyme and an energy field. This is found persuasive, and claims 1-17 and 18-28 are rejoined for examination. However, in the original restriction claims 29-44, drawn to an intact NP probe, should have been included as a separate group, since these probes can be used in other methods, for example, detection of enzyme binding. Therefore claims 29-44 are not going to be examined with claims 1-28.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 29-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

- It does not identify the mailing or post office address of each inventor. A mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

- It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.

Drawings

4. The drawings (FIG. 6) are objected to under 37 CFR 1.83(a) because they fail to show details of the synthesis processes as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
5. The drawings are objected to because: the description of Fig. 4 on page 14, line 6, states that it represents BODIPY conjugated to dTTT, whereas the legend to Figure 4 states that it is dTTP-BQS-BTR. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description:
 - a) in Fig. 7, there is a reference sign "73",
 - b) in Fig. 9, there is a reference sign "97".A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: there are no reference

signs "1000", "1072a" and "1072b". A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

8. The disclosure is objected to because of the following informalities: the first paragraph of the specification contains a reference to a related application identified by Attorney docket number. The applications should be identified by PTO or WIPO application or patent numbers.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 1 is indefinite because of the limitation "...NP probe...". It is not clear what "NP" stands for.

B) Claim 1 is indefinite because it is not clear what is the "intact NP probe". The claim's preamble states "A method for separating an intact NP probe from a phosphate detectable moiety...", whereas in step a) there is "...enzymatic cleavage of said intact NP probe...", therefore the probe is not intact anymore.

C) Claim 3 recites the limitation "said charge-switch nucleotide phosphate" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

D) Claim 4 is incomprehensible. It is not clear into what the probe is incorporated and how.

E) Claim 6 recites the limitation "said polymerase" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

11. Claims 1-28 are provisionally rejected under the judicially created doctrine of double patenting over claims 22-36 of copending Application No. 09/876,374. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: methods for separating labeled nucleotide phosphate from its detectable moiety, by subjecting the labeled nucleotide phosphate to enzymatic cleavage and separating the cleaved, now charged detectable moiety in an energy field.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

13. Claims 1-4, 7, 10-14, 16-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Klaubert et al. (U.S. Patent No. 6,323,186 B1).

Klaubert et al. teach nucleotides with fluorescent labels bound to the phosphate moiety, where the nucleotide is a mono-, di- or triphosphate. The nucleotide's sugar can be a ribose, deoxyribose or dideoxyribose, and the possible bases are adenine, guanine, thymine, cytosine, uracil or xanthine. In one embodiment the nucleotide is a triphosphate, with the label bound to the terminal γ -phosphate (col. 2, lines 29-51; col. 3, lines 18-67; col. 4, lines 1-43).

The labeled nucleotides are used in enzymatic assays involving cleavage of the labeled nucleotides, where the cleavage occurs between the ribose moiety and the phosphate chain, and in the case when the nucleotide is a polyphosphate, the cleavage can occur between the α - and β -phosphate, between the β - and γ -phosphate or between the fluorophore and the γ -phosphate, generating charged, fluorescent phosphate moiety. One of the enzymes which can be used is a phosphodiesterase (col. 7, lines 49-67; col. 8, lines 15-18).

Detection of the cleavage reaction is facilitated by separation of the cleavage product from the nucleotide in the electric field by electrophoresis. The fluorescence of the released labeled phosphate can be detected using CCD cameras, photodiodes, fluorometers, etc.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klaubert et al. as applied to claims 1 and 13 above, and further in view of Walt et al. (U.S. Patent No. 5,814,524).

A) Claim 15 is drawn to the detection of the phosphate detectable moiety by optical fiber sensor.

B) The teachings of Klaubert et al. are described above. Klaubert et al. do not teach detection of the labeled phosphate by fiber optic sensor.

C) Walt et al. teach a fiber optic sensor for detection of analytes in different types of samples (Abstract; col. 5, lines 1-45).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the fiber optic sensor of Walt et al. in the phosphate detection method of Klaubert et al. The motivation to do so, expressly provided by Walt et al., would have been that the sensor was used to detect used to detect multiple analytes with high sensitivity.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization

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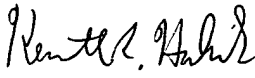
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where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
May 14, 2002

TS


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

5/14/02